Page 10, line 12, replace "one or more holes 254, 256" with --one or more holes 254a, 256a--; and

Page 14, line 34, replace "staples through holes 254 and/or 256" with --staples through holes 254a and/or 256a--.

IN THE DRAWINGS

A marked-up version of amended Fig. 14, amended Fig. 16, and amended Fig. 17 with the proposed changes shown in red, are attached hereto as Exhibit C.

REMARKS

Figures 14, 16, and 17 have been amended. In these figures, the reference element numbers 254 and 256 have been changed to 254a and 256a, respectively. The Specification has been amended to reflect these proposed changes to the drawings. No new matter has been added.

Also, enclosed herewith are nineteen (19) sheets of substitute, formal drawings consisting of Figs. 1-32 in compliance with 37 C.F.R. § 1.84. Applicants respectfully request that the attached drawings be substituted for the drawings originally filed in this application.

No fee is believed to be due for this submission. Should any additional fees be required, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully Submitted,

Date: April 18, 2001

For: Brian M. Poissant

Brian J. Malm Reg. No. 44,895
For: Brian M. Poissant Reg. No. 28,462

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Enclosures

EXHIBIT A - MARKED-UP VERSION OF

SPECIFICATION PAGE 10 AND SPECIFICATION PAGE 14

238 is provided between graft interface portion 214 and body 12. According to the embodiment illustrated in Fig.14, bone block cage 217 is a one-piece structure having longitudinal wall stem sections 229 and cut-out portions 231. Distal end 232 of bone block cage 217 has a circular opening 235 through which a bone plug or block may be inserted. As illustrated in Figs. 16 and 17, proximal end 239 of cage 217 has a wall 245 having flexible post 236 extending longitudinally away from cage portion 217 for inserting into recess 18 in body 12 and attaching the bone block cage thereto. Wall sections 229 are preferably formed on opposite sides of cage 217 so that a bone block may be inserted therebetween.

After insertion of a bone block, wall sections 229 may be crimped inwardly to hold the bone block in place. Instead of or in addition to crimping a bone block in cage 217, wall sections 229 may be provided with one or more holes 254a, 256a so that one or more staples (not shown) may be inserted through wall sections 229 and the bone block to hold the bone block in the cage. Cut-out portions 231 (Fig. 15) provide an openness to the cage 217 structure to encourage bone regeneration between a bone block in cage 217 and a bone tunnel in which the cage is inserted.

Another embodiment, graft fixation device 310, illustrated in Figs. 18-25 may be useful for bone-tendon-bone reconstruction. Graft fixation device 310 preferably includes a graft interface member 314 which includes a helical screw member 317 for insertion into a bone plug and a swivel connector 318 for connection to body 12. Rotatable connection 338 is provided between a swivel connector 318 and threaded body 12. Swivel connector 318 includes a wall portion 345 having a flexible post 336 extending longitudinally away from wall portion 345 for inserting into recess 18 in body 12. Flexible post 336 may be configured and structured as flexible post 36 described above. Swivel connector 318 is independently rotatable with respect to body 12 about longitudinal axis 344.

Wall portion 345 may be hexagonally-shaped as shown having side surfaces 362 to fit a wrench or other instrument to rotate swivel connector 318. Slots 364 may be formed in side surfaces 362 with a passageway 366 extending through wall portions 345 between slots 364 as shown in Figs. 23 and 24.

Helical screw member 317 has a proximal hook portion 368 at its proximal end 339 for connecting to swivel connector 318. Proximal hook portion 368 has a curved end section 370 connected to straight-extending section 372 followed by curved middle section 374 which transitions to helical screw section 376 which engages a bone portion of a BTB graft. Helical screw member 317 is connected to the swivel connector 318 so that

Preliminarily, a soft-tissue graft or a bone-tendon-bone graft is obtained or harvested and is secured to an appropriate graft interface portion, such as, for example, one of the embodiments described above. A soft-tissue graft, for example, may be attached to an embodiment of the fixation device which has an eyelet loop portion, such as the embodiment illustrated in Figs. 1 - 6. An end of a bone-tendon-bone graft, on the other hand, is preferably attached to an embodiment capable of securely holding a bone block or bone plug, such as, for example, one of the embodiments illustrated in Figs. 7-13, 14-17 or 18-25. Preferably, the graft interface member 14, 114, 214 or 314 is connected to body 12 by a permanent, rotatable connection such as, for example, rotatable coupling 38, 138, 238, 338 between the interface member and the implant body. Such a connection ensures that the implant/graft fixation device is securely and permanently held together, yet the implant body portion 12 is free to rotate about the longitudinal axis 44 of the device independently of a graft attached to the interface member 14, 114, 214 or 314.

The fixation device may be inserted and affixed in a bone tunnel according to a method wherein graft interface member 14, 114, 214 or 314 is preferably connected to body 12 prior to attachment of the graft to the interface member. Any one of the embodiments of the fixation device described hereinabove may be selected for use with the method, depending on the type of graft which is chosen. For example, a soft tissue graft is preferably attached to fixation device 10 at enclosed loop 32. Preferably, the soft tissue graft is sutured to itself and/or eyelet loop 32 to ensure that the graft will not fall off fixation device 10. A bone-tendon-bone graft may be attached to a fixation device 110, 210 or 310 which secures the bone block at one end of the graft to the fixation device or implant.

When using fixation device 110, as exemplified by Figs. 7 - 13, a bone block at one end of the graft may be placed into cage bottom 119 (shown in Fig. 8) and cage top 121 may then be attached to the cage bottom by, for example, inserting and snapping detents 123 into fittings 125. Serrations 133 bite into the bone block, while windows 131 provide openings to promote bony ingrowth and regeneration between the bone block and a bone tunnel into which the fixation device is to be inserted. Alternatively, a graft having a bone block at one end may be attached to fixation device 210, which provides a one-piece bone block cage 217 such as that illustrated in Figs. 14-17. To use the one-piece bone block cage embodiment, the bone block at one end of the graft is inserted axially into opening 235 at distal end 232 of cage 217. The bone block may be secured to cage 217 by one of several methods such as, for example, crimping longitudinal wall sections 229 against the bone block or by inserting one or more staples through holes 254a and/or 256a into the bone block.

EXHIBIT B - SUBSTITUTE SPECIFICATION PAGE 10

AND SUBSTITUTE SPECIFICATION PAGE 14

238 is provided between graft interface portion 214 and body 12. According to the embodiment illustrated in Fig.14, bone block cage 217 is a one-piece structure having longitudinal wall stem sections 229 and cut-out portions 231. Distal end 232 of bone block cage 217 has a circular opening 235 through which a bone plug or block may be inserted. As illustrated in Figs. 16 and 17, proximal end 239 of cage 217 has a wall 245 having flexible post 236 extending longitudinally away from cage portion 217 for inserting into recess 18 in body 12 and attaching the bone block cage thereto. Wall sections 229 are preferably formed on opposite sides of cage 217 so that a bone block may be inserted therebetween.

After insertion of a bone block, wall sections 229 may be crimped inwardly to hold the bone block in place. Instead of or in addition to crimping a bone block in cage 217, wall sections 229 may be provided with one or more holes 254a, 256a so that one or more staples (not shown) may be inserted through wall sections 229 and the bone block to hold the bone block in the cage. Cut-out portions 231 (Fig. 15) provide an openness to the cage 217 structure to encourage bone regeneration between a bone block in cage 217 and a bone tunnel in which the cage is inserted.

Another embodiment, graft fixation device 310, illustrated in Figs. 18-25 may be useful for bone-tendon-bone reconstruction. Graft fixation device 310 preferably includes a graft interface member 314 which includes a helical screw member 317 for insertion into a bone plug and a swivel connector 318 for connection to body 12. Rotatable connection 338 is provided between a swivel connector 318 and threaded body 12. Swivel connector 318 includes a wall portion 345 having a flexible post 336 extending longitudinally away from wall portion 345 for inserting into recess 18 in body 12. Flexible post 336 may be configured and structured as flexible post 36 described above. Swivel connector 318 is independently rotatable with respect to body 12 about longitudinal axis 344.

Wall portion 345 may be hexagonally-shaped as shown having side surfaces 362 to fit a wrench or other instrument to rotate swivel connector 318. Slots 364 may be formed in side surfaces 362 with a passageway 366 extending through wall portions 345 between slots 364 as shown in Figs. 23 and 24.

Helical screw member 317 has a proximal hook portion 368 at its proximal end 339 for connecting to swivel connector 318. Proximal hook portion 368 has a curved end section 370 connected to straight-extending section 372 followed by curved middle section 374 which transitions to helical screw section 376 which engages a bone portion of a BTB graft. Helical screw member 317 is connected to the swivel connector 318 so that

Preliminarily, a soft-tissue graft or a bone-tendon-bone graft is obtained or harvested and is secured to an appropriate graft interface portion, such as, for example, one of the embodiments described above. A soft-tissue graft, for example, may be attached to an embodiment of the fixation device which has an eyelet loop portion, such as the embodiment illustrated in Figs. 1 - 6. An end of a bone-tendon-bone graft, on the other hand, is preferably attached to an embodiment capable of securely holding a bone block or bone plug, such as, for example, one of the embodiments illustrated in Figs. 7-13, 14-17 or 18-25. Preferably, the graft interface member 14, 114, 214 or 314 is connected to body 12 by a permanent, rotatable connection such as, for example, rotatable coupling 38, 138, 238, 338 between the interface member and the implant body. Such a connection ensures that the implant/graft fixation device is securely and permanently held together, yet the implant body portion 12 is free to rotate about the longitudinal axis 44 of the device independently of a graft attached to the interface member 14, 114, 214 or 314.

The fixation device may be inserted and affixed in a bone tunnel according to a method wherein graft interface member 14, 114, 214 or 314 is preferably connected to body 12 prior to attachment of the graft to the interface member. Any one of the embodiments of the fixation device described hereinabove may be selected for use with the method, depending on the type of graft which is chosen. For example, a soft tissue graft is preferably attached to fixation device 10 at enclosed loop 32. Preferably, the soft tissue graft is sutured to itself and/or eyelet loop 32 to ensure that the graft will not fall off fixation device 10. A bone-tendon-bone graft may be attached to a fixation device 110, 210 or 310 which secures the bone block at one end of the graft to the fixation device or implant.

When using fixation device 110, as exemplified by Figs. 7 - 13, a bone block at one end of the graft may be placed into cage bottom 119 (shown in Fig. 8) and cage top 121 may then be attached to the cage bottom by, for example, inserting and snapping detents 123 into fittings 125. Serrations 133 bite into the bone block, while windows 131 provide openings to promote bony ingrowth and regeneration between the bone block and a bone tunnel into which the fixation device is to be inserted. Alternatively, a graft having a bone block at one end may be attached to fixation device 210, which provides a one-piece bone block cage 217 such as that illustrated in Figs. 14-17. To use the one-piece bone block cage embodiment, the bone block at one end of the graft is inserted axially into opening 235 at distal end 232 of cage 217. The bone block may be secured to cage 217 by one of several methods such as, for example, crimping longitudinal wall sections 229 against the bone block or by inserting one or more staples through holes 254a and/or 256a into the bone block.

EXHIBIT C - MARKED-UP VERSION OF AMENDED DRAWING FIG. 14, AMENDED DRAWING FIG. 16, AND AMENDED DRAWING FIG. 17

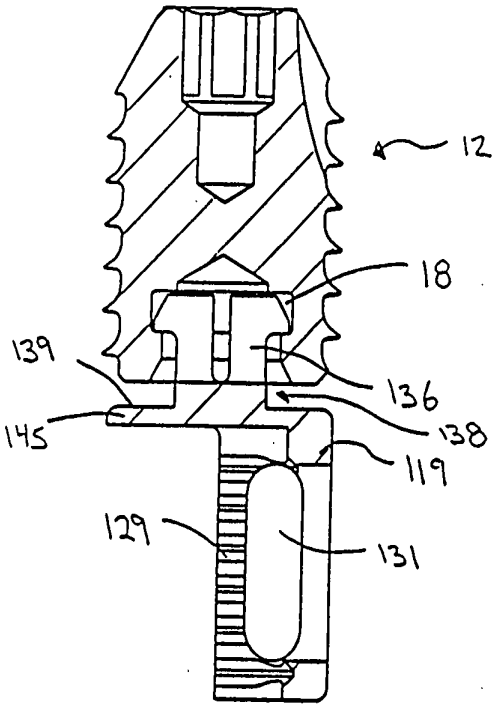
12
18
139
136
145
138
119
129
131

Fig. 13

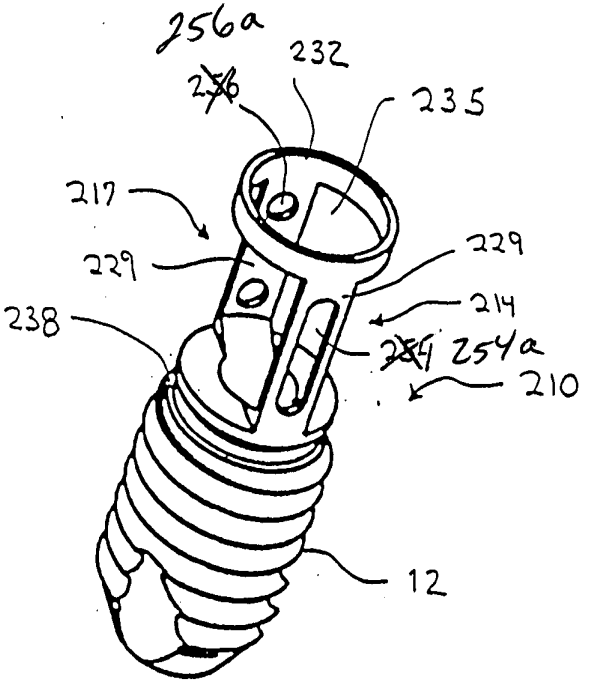
256a
232
256
235
217
229
229
214
238
254
254a
210
12

Fig. 14

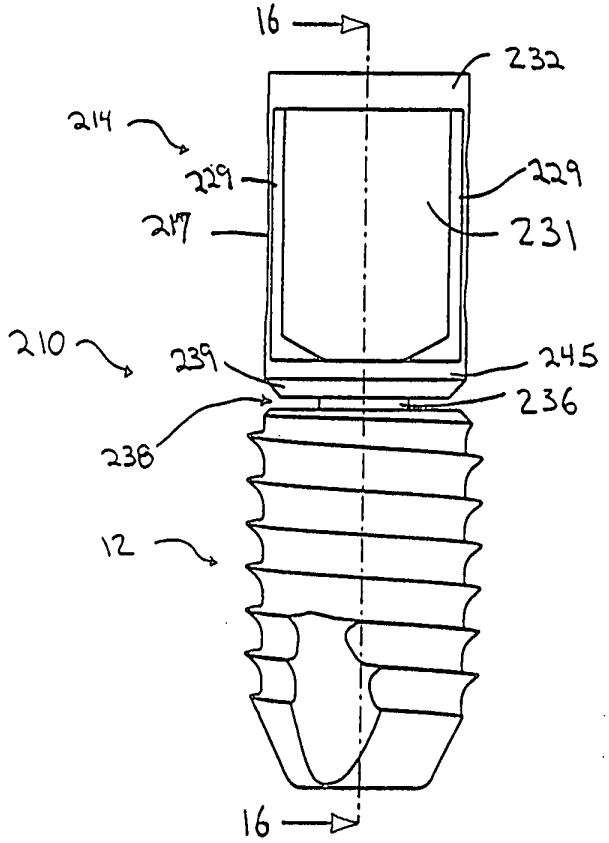
16
232
214
229
229
217
231
210
239
245
236
238
12
16

Fig. 15

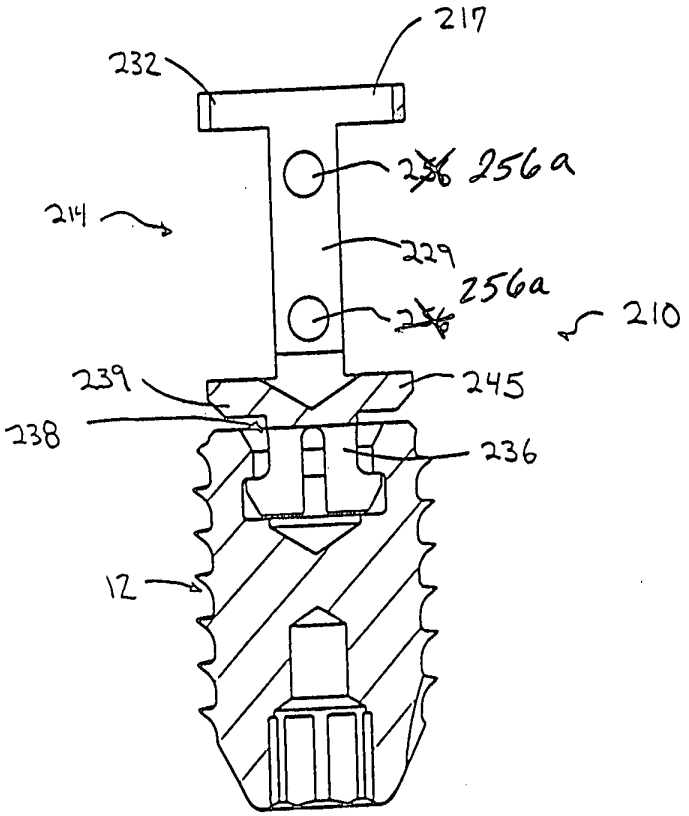
217
232
256a
214
229
256a
210
239
245
238
236
12

Fig. 16

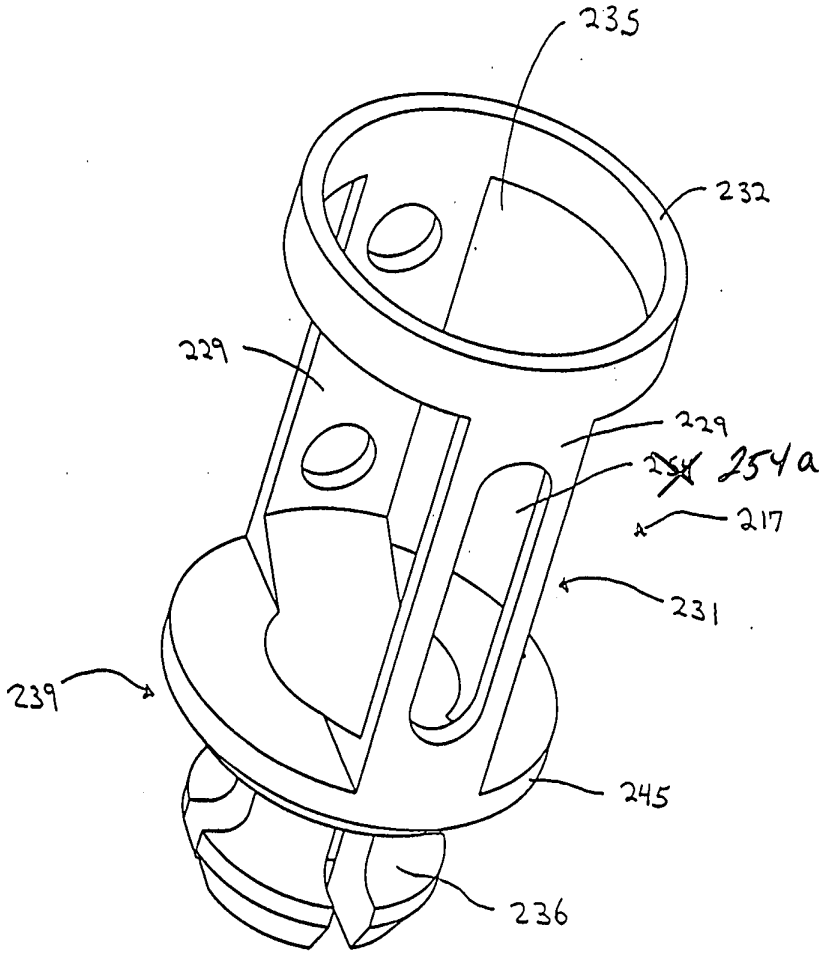

Fig. 17